

Notice of Public Hearing

Pursuant to Section 22215 of Public Act 306 of 1969, as amended, the Michigan Department of Health and Human Services (MDHHS) will hold a hearing on Certificate of Need (CON) Review Standards.

Date: Thursday, July 29, 2021

Time: 9:30 a.m.

Topic: Positron Emission Tomography (PET) Scanner Services and Hospital Beds Public Hearing

Location: South Grand Building
333 S. Grand Avenue, 1st Floor
Conference Room 1A
Lansing, MI 48933

Virtual: **Members of the public may attend virtually**
Feel free to join from your PC, Mac, Linux, iOS or Android:
<https://michigan-host.zoom.us/j/89802864024>

Or by Telephone:
USA (215) 446-3656
USA (888) 363-4734 (US Toll Free)
Conference code: 212089



POSITRON EMISSION TOMOGRAPHY (PET) SCANNER SERVICES

The proposed language changes include the following:

1. Section 2(1): Added and moved/modified definitions as follows:

(c) "COMPREHENSIVE FIXED PET REFERRAL SERVICE" MEANS A PET SCANNER SERVICE THAT IS LOCATED IN THE SAME OR IN A CONTIGUOUS BUILDING AS A FIXED CYCLOTRON-EQUIPPED RADIOPHARMACY CAPABLE OF PRODUCING A BROAD SPECTRUM OF RADIOISOTOPES, INCLUDING THOSE WITH SHORT HALF-LIVES, AND INCLUDES AT LEAST ONE OF THE FOLLOWING FDA-APPROVED PET SCANNERS:

- (i) FIXED WHOLE-BODY PET/CT,
- (ii) FIXED DIGITAL PET/CT SCANNER, OR
- (iii) FIXED PET/MRI SCANNER HYBRID.

(g) "FIXED CYCLOTRON" MEANS A FIXED PARTICLE ACCELERATOR USED FOR THE PRODUCTION OF MULTIPLE MEDICAL ISOTOPES.

(h) "FIXED DIGITAL PET/CT SCANNER" MEANS A FIXED PET/CT HYBRID WITH SILICON PHOTOMULTIPLIERS (SIPM) WITH DIGITAL READOUT FOR HIGH-RESOLUTION IMAGE RECONSTRUCTION.

(i) "FIXED WHOLE BODY PET/CT SCANNER" MEANS A FIXED PET/CT SCANNER WITH AN AXIAL FIELD OF VIEW OF >130CM.

2. Section 3(4): For conversion from mobile to fixed PET services, a proposed 11.8% reduction. Metropolitan statistical area counties would be reduced from 1,700 PET equivalents to 1,500 PET equivalents, and rural or micropolitan statistical area counties would be reduced from 1,500 PET equivalents to 1,325 PET equivalents. This change would improve patient care and access without impacting cost.
3. New Section 10: Added requirements for a pilot program to initiate, replace, expand or acquire a comprehensive fixed PET referral service. As a pilot program, this will allow for the collection and review of data regarding utilization to determine future updates of the PET CON review standards.

(1) AN APPLICANT PROPOSING TO INITIATE A COMPREHENSIVE FIXED PET REFERRAL SERVICE SHALL DEMONSTRATE ALL OF THE FOLLOWING:

(a) THE APPLICANT SHALL PROVIDE A SIGNED LETTER(S) OF SUPPORT FROM A HOSPITAL(S) AND/OR PHYSICIAN PRACTICE(S) INDICATING THE WILLINGNESS OF THE HOSPITAL(S) AND/OR PHYSICIAN PRACTICE(S) TO PROVIDE REFERRALS AND CONSULTING SERVICES TO THE APPLICANT FOR THE SPECIALTIES LISTED BELOW:

- (i) CARDIOLOGY
- (ii) ONCOLOGY
- (iii) RADIATION ONCOLOGY/THERAPY
- (iv) NEUROLOGY

(b) THE APPLICANT SHALL HAVE A FIXED CYCLOTRON.

(c) THE APPLICANT SHALL HAVE A RADIOPHARMACY ONSITE THAT WILL COMBINE CYCLOTRON-PRODUCED RADIONUCLIDE TRACERS WITH PHARMACEUTICAL COMPONENTS FOR PURPOSES OF ONSITE PATIENT ADMINISTRATION.

(d) THE APPLICANT'S RADIOPHARMACY SHALL SUPPORT THE DEVELOPMENT OF RADIOPHARMACEUTICALS FOR USE IN DIAGNOSTIC AND THERANOSTIC APPLICATIONS.

(e) THE APPLICANT IS PROPOSING NO MORE THAN TWO FIXED PET SCANNERS.

(f) THE APPLICANT AGREES TO OPERATE THE COMPREHENSIVE FIXED PET REFERRAL SERVICE IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 12 OF THESE STANDARDS INCLUDING, BUT NOT LIMITED TO, THE FOLLOWING:

(i) THE APPLICANT SHALL BECOME ACCREDITED BY THE AMERICAN COLLEGE OF RADIOLOGY (ACR), THE INTERSOCIETAL ACCREDITATION COMMISSION (IAC) OR ANY OTHER NATIONAL ACCREDITATION BODY ACCEPTABLE TO THE DEPARTMENT.

(ii) THE APPLICANT'S RADIOPHARMACY SHALL BE LICENSED BY THE MICHIGAN BOARD OF PHARMACY.

(2) AN APPLICANT PROPOSING TO INITIATE A COMPREHENSIVE FIXED PET REFERRAL SERVICE SHALL NOT BE REQUIRED TO PROJECT PET DATA UNITS.

(3) AN APPLICANT PROPOSING TO REPLACE A COMPREHENSIVE FIXED PET REFERRAL SERVICE SHALL DEMONSTRATE ANY ONE OF THE FOLLOWING:

(a) THE APPLICANT MEETS THE REQUIREMENTS OF SECTION 4(1).

(b) THE APPLICANT IS PROPOSING TO REPLACE A COMPREHENSIVE FIXED PET REFERRAL SERVICE AND ITS EXISTING PET SCANNER UNIT(S) TO A NEW SITE AND MEETS THE FOLLOWING:

- (i) THE PROPOSED SITE IS WITHIN THE PLANNING AREA.
- (ii) THE EXISTING FIXED PET SCANNER(S) PERFORMED 500 PET EQUIVALENTS PER FIXED SCANNER IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT.
- (iii) THE EXISTING COMPREHENSIVE FIXED PET REFERRAL SERVICE HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE ON WHICH THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.
- (iv) THE FIXED PET SCANNER(S) WILL BE LOCATED IN THE SAME BUILDING OR IN A CONTIGUOUS BUILDING AS A FIXED CYCLOTRON-EQUIPPED RADIOPHARMACY.

(4) AN APPLICANT PROPOSING TO EXPAND A COMPREHENSIVE FIXED PET REFERRAL SERVICE SHALL DEMONSTRATE THAT IT MEETS THE REQUIREMENTS OF SECTION 5.

(5) AN APPLICANT PROPOSING TO ACQUIRE A COMPREHENSIVE FIXED PET REFERRAL SERVICE OR ITS SCANNER(S) SHALL DEMONSTRATE THAT IT MEETS THE REQUIREMENTS OF SECTION 6.

(6) THE COMMISSION MAY DECIDE TO HAVE THE REQUIREMENTS OF THE PILOT PROGRAM DESCRIBED IN THIS SECTION BECOME A PERMANENT PART OF THE PET SCANNER SERVICES STANDARDS. IF THE COMMISSION DOES NOT TAKE ACTION TO MAKE THE PILOT PROGRAM A PERMANENT PART OF THE STANDARDS, THE PROVISIONS OF THIS SECTION WILL EXPIRE ON SEPTEMBER 30, 2027 AND AFTER THAT DATE WILL BE OF NO FURTHER FORCE AND EFFECT. ANY APPLICANT SEEKING TO PARTICIPATE IN THE PILOT PROGRAM DESCRIBED IN THIS SECTION MUST SUBMIT ITS APPLICATION ON OR BEFORE SEPTEMBER 1, 2023. THESE PROVISIONS SHALL NOT BE APPLICABLE TO ANY APPLICATION SUBMITTED AFTER SEPTEMBER 1, 2023.

4. Section 12(9): Added project delivery requirements for a comprehensive fixed PET referral service approved under Section 10 of the standards.

(9) FOR A COMPREHENSIVE FIXED PET REFERRAL SERVICE APPROVED UNDER SECTION 10, COMPLIANCE WITH THE FOLLOWING TERMS:

(a) THE APPLICANT SHALL BECOME ACCREDITED BY AMERICAN COLLEGE OF RADIOLOGY (ACR), INTERSOCIETAL ACCREDITATION COMMISSION (IAC) OR ANY OTHER NATIONAL ACCREDITATION BODY ACCEPTABLE TO THE DEPARTMENT WITHIN 18 MONTHS OF OPERATION AND SHALL MAINTAIN ACCREDITATION ON AN ON-GOING BASIS.

(b) THE APPLICANT MEETS THE REQUIREMENTS LISTED IN SECTION 11(1) – (8), AS APPLICABLE.

(c) THE APPLICANT'S RADIOPHARMACY SHALL BE LICENSED BY THE MICHIGAN BOARD OF PHARMACY WITHIN 12 MONTHS OF OPERATION AND SHALL CONTINUE TO BE LICENSED ON AN ONGOING BASIS.

(d) THE APPLICANT SHALL HAVE EQUIPMENT AND SUPPLIES ONSITE TO HANDLE CLINICAL EMERGENCIES THAT MIGHT OCCUR IN THE UNIT.

(e) PET SERVICE STAFF SHALL BE TRAINED IN CPR AND OTHER APPROPRIATE EMERGENCY INTERVENTIONS.

(f) THE APPLICANT SHALL ESTABLISH AND MAINTAIN: (i) A STANDING MEDICAL STAFF AND GOVERNING BODY (OR ITS EQUIVALENT) THAT PROVIDES FOR THE

MEDICAL AND ADMINISTRATIVE CONTROL OF THE ORDERING AND UTILIZATION OF PET PATIENT PROCEDURES, AND (ii) A FORMAL PROGRAM OF UTILIZATION REVIEW AND QUALITY ASSURANCE.

(g) BY APRIL 30TH OF EACH YEAR, ANTHE APPLICANT SHALL PROVIDE ANNUAL REPORTS TO THE DEPARTMENT REGARDING ALL DIAGNOSTIC SCANS PERFORMED USING RADIOISOTOPES OTHER THAN FDG IN THE PRECEDING CALENDAR YEAR. THIS REPORTING REQUIREMENT SHALL CONTINUE FOR A PERIOD OF 7 YEARS AND IS IN ADDITION TO THE REQUIREMENTS OF SECTION 12(4)(b). THESE THE DATA INCLUDED IN THE REPORT SHALL, AT A MINIMUM, INCLUDE:

- (i) PATIENT AND REFERRING PHYSICIAN ZIP CODES,
- (ii) NUMBER OF SCANS BY DIAGNOSIS AND/OR RADIOTRACER,
- (iii) NUMBER OF PEDIATRIC (LESS THAN 18 YEARS OLD) AND ADULT SCANS,
- (iv) AVERAGE EQUIPMENT TIME BY VISIT TYPE, AS AVAILABLE, AND
- (v) NUMBER OF SCANS PERFORMED AS PART OF A RESEARCH STUDY.

5. Other technical edits.



CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR HOSPITAL BEDS

The proposed language changes include the following:

1. Section 2(1): Added and moved/modified definitions as follows:

(i) "Compare group OR COMPARATIVE REVIEW GROUP" means the applications, OTHER THAN APPLICATIONS APPLYING UNDER SECTION 6(5), that have been grouped for the same type of project in the same hospital group and are being reviewed comparatively in accordance with the con rules. FOR APPLICATIONS APPLYING UNDER SECTION 6(5), COMPARE GROUP OR COMPARATIVE REVIEW GROUP MEANS APPLICATIONS THAT HAVE BEEN GROUPED FOR THE SAME TYPE OF PROJECT AND ARE PROPOSING SITES WITHIN A 60-MINUTE TRAVEL TIME AND ARE BEING REVIEWED COMPARATIVELY IN ACCORDANCE WITH THE CON RULES.

(o) "GEOGRAPHICALLY underserved area" means those geographic areas THAT ARE MORE THAN 30-minuteS drive time FROM an existing licensed acute care hospital with 24 hour/7 days a week emergency room services USING ESRI'S ONLINE NETWORK ANALYST SERVICES (OR A COMPARABLE SOURCE). *(This definition replaces the former definition "underserved area.")*

(z) "Limited access area" means A POTENTIAL HOSPITAL LOCATION BOTH WITH A BED NEED OF 10 BEDS OR MORE AND AN UNDERSERVED POPULATION PERCENT OF 50% OR MORE, as identified on the state of Michigan CON web site. Limited access areas shall be redetermined IN THE FOLLOWING CIRCUMSTANCES:

- (i) EACH TIME THE BED NEED METHODOLOGY IS REDETERMINED,
- (ii) when a new hospital has been approved, or
- (iii) WHEN an existing hospital closes.

(kk) "POTENTIAL HOSPITAL LOCATION" MEANS A 1KM HEXAGON REGION. THE CENTER POINT OF WHICH IS LOCATED BOTH IN A GEOGRAPHICALLY UNDERSERVED AREA AND ON LAND (NOT WATER).

(rr) "Replacement zone" means a proposed licensed site that (i) is in the same hospital group as the existing licensed site as determined by the Department in accord with Section 3 of these standards and IS on the same site, on a contiguous site, or on a site within 2 miles (5 miles for IRF beds) of the existing licensed site if the existing licensed site is located in a county with a population of 200,000 or more, or on a site within 5 miles (10 miles for IRF beds) of the existing licensed site if the existing licensed site is located in a county with a population of less than 200,000 OR (ii) QUALIFIES AS AN ENHANCED REPLACEMENT ZONE.

(uu) "VERIFIABLE DATA" MEANS DATA (PATIENT DAYS) FROM THE MOST RECENT ANNUAL SURVEY OR MORE RECENT DATA THAT CAN BE VALIDATED BY THE DEPARTMENT.

2. Section 4(2): Updated the methodology to determine limited access areas and the bed need for those areas. The proposed updated methodology utilizes travel time and population with defined bed need thresholds.

(2) The determination of limited access areas AND THEIR HOSPITAL BED NEED shall be made using the methodology detailed in "A Methodology for Determining LIMITED ACCESS AREAS" by Paul L. Delamater, 2021, WHICH METHODOLOGY IS SUMMARIZED as follows:

(a) CALCULATE THE AVERAGE YEARLY PATIENT DAY USE RATE OF MICHIGAN RESIDENTS IN THE BASE YEAR AS FOLLOWS:

(i) SUM ALL PATIENT DAYS FROM ALL HOSPITAL DISCHARGES FOR MICHIGAN RESIDENTS IN THE BASE YEAR, EXCLUDING all hospital discharges for normal newborns (DRG 391 prior to 2008, DRG 795 thereafter) and psychiatric patients (ICD-9-CM codes 290 through 319, see Appendix D for ICD-10-CM Codes, as a principal diagnosis).

(ii) ACQUIRE THE ESTIMATED MICHIGAN POPULATION IN THE BASE YEAR FROM THE US CENSUS BUREAU.

(iii) DIVIDE THE SUMMED PATIENT DAYS CALCULATED IN (i) BY THE ESTIMATED MICHIGAN POPULATION ACQUIRED IN (ii) TO CALCULATE THE AVERAGE YEARLY PATIENT DAY USE RATE.

(b) IDENTIFY GEOGRAPHICALLY UNDERSERVED AREAS AS FOLLOWS:

(i) USING ESRI'S ONLINE NETWORK ANALYST SERVICES (OR A COMPARABLE SOURCE), CREATE 30-MINUTE DRIVE TIME SERVICE AREAS AROUND EACH EXISTING LICENSED ACUTE CARE HOSPITAL WITH 24 HOUR/7 DAYS A WEEK EMERGENCY ROOM SERVICES.

(ii) IDENTIFY REGIONS GREATER THAN A 30-MINUTE DRIVE FROM THE NEAREST EXISTING HOSPITAL BY REMOVING THE 30-MINUTE SERVICE AREAS FROM THE STATE GEOGRAPHIC FOOTPRINT. THE REMAINING REGIONS ARE THE GEOGRAPHICALLY UNDERSERVED AREAS.

(c) IDENTIFY POTENTIAL HOSPITAL LOCATIONS AS FOLLOWS:

(i) CREATE A HEXAGON TESSELATION OVER THE ENTIRE STATE WITH 1KM DISTANCE BETWEEN THE CENTER POINT OF EVERY HEXAGON.

(ii) SUBSET THE HEXAGONS TO INCLUDE ONLY THOSE HEXAGONS WITH A CENTER POINT THAT IS LOCATED WITHIN A GEOGRAPHICALLY UNDERSERVED AREA AND ON LAND. FOR PURPOSES OF THIS SUBSECTION, ON LAND MEANS THOSE US CENSUS BLOCK GROUPS THAT ARE NOT 100% COVERED BY WATER. THE SET OF REMAINING HEXAGONS ARE THE POTENTIAL HOSPITAL LOCATIONS.

(d) FOR EACH POTENTIAL HOSPITAL LOCATION, CALCULATE THE BED NEED AND THE UNDERSERVED POPULATION PERCENT AS FOLLOWS:

(i) USING ESRI'S ONLINE NETWORK ANALYST SERVICES (OR A COMPARABLE SOURCE), CREATE A 30-MINUTE DRIVE TIME SERVICE AREA AROUND THE HEXAGON CENTER POINT.

(ii) IDENTIFY THE NUMBER OF PEOPLE RESIDING WITHIN THE 30-MINUTE SERVICE AREA USING US CENSUS BLOCK CENTROIDS WITH UPDATED POPULATION INFORMATION.

(iii) ASSIGN EACH POPULATION AS CURRENTLY UNDERSERVED OR CURRENTLY SERVED BY GEOGRAPHICALLY OVERLAYING THE US CENSUS BLOCK CENTROIDS (WITH UPDATED POPULATION INFORMATION) USED IN (ii) WITH THE GEOGRAPHICALLY UNDERSERVED AREAS IDENTIFIED IN (b). SUM THE NUMBER OF PEOPLE IN BOTH GROUPS TO DETERMINE THE TOTAL POPULATION.

(iv) MULTIPLY THE UNDERSERVED POPULATION TOTAL BY THE AVERAGE YEARLY PATIENT DAY USE RATE OF MICHIGAN RESIDENTS IN THE BASE YEAR AS CALCULATED IN SECTION 4(2)(a) TO CALCULATE THE EXPECTED NUMBER OF YEARLY PATIENT DAYS. FOLLOW THE STEPS IN SECTION 4(1)(h) – (j) TO CALCULATE THE BED NEED FOR THE HOSPITAL LOCATION.

(v) DIVIDE THE UNDERSERVED POPULATION TOTAL BY THE TOTAL POPULATION AS DETERMINED IN (iii), AND MULTIPLY BY 100 TO CALCULATE THE UNDERSERVED POPULATION PERCENT.

(e) REMOVE ALL POTENTIAL HOSPITAL LOCATIONS WITH A BED NEED OF LESS THAN 10 BEDS OR WITH AN UNDERSERVED POPULATION PERCENT OF LESS THAN 50%. THE REMAINING POTENTIAL HOSPITAL LOCATIONS ARE THE LIMITED ACCESS AREAS.

3. Section 6(5): Updated the requirements to initiate a new hospital in a limited access area.

4. Section 7(3): The replacement zone was revised to give hospitals greater flexibility to optimize access and to optimally serve their community.

(3) The applicant shall demonstrate that the new licensed site is in the replacement zone OR IN THE ENHANCED REPLACEMENT ZONE. TO QUALIFY AS AN ENHANCED REPLACEMENT ZONE, THE FOLLOWING REQUIREMENTS SHALL BE MET:

(a) THE EXISTING LICENSED SITE SHALL:

(i) BE LOCATED IN A COUNTY WITH A POPULATION OF 200,000 OR LESS, AND

(ii) BE THE ONLY LICENSED HOSPITAL SITE IN THAT COUNTY THAT REPORTED PROVIDING EMERGENCY SERVICES ON THE MOST RECENT CON ANNUAL SURVEY AS OF THE DATE OF THE APPLICATION; AND

(b) THE PROPOSED LICENSED SITE SHALL:

(i) BE IN THE SAME HOSPITAL GROUP AS THE EXISTING LICENSED SITE AS DETERMINED BY THE DEPARTMENT IN ACCORD WITH SECTION 3 OF THESE STANDARDS,

(ii) BE ON A SITE WITHIN 10 MILES OF THE EXISTING LICENSED SITE,

(iii) BE ON A SITE WITHIN THE SAME COUNTY AS THE EXISTING LICENSED SITE OR IN AN ADJACENT COUNTY THAT DOES NOT CURRENTLY HAVE A LICENSED HOSPITAL SITE THAT OFFERS EMERGENCY SERVICES, AND

(iv) BE ON A SITE 10 OR MORE MILES FROM ALL OTHER LICENSED HOSPITALS SITES THAT OFFER EMERGENCY SERVICES.

5. Section 12(4): Updated the comparative review requirements for limited access areas.

(4) If the comparative review group involves limited access area(S), each qualifying project will be awarded points based on the BED NEED OF EACH APPLICANT'S CHOSEN LIMITED ACCESS AREA. THE APPLICANT PROPOSING TO LOCATE A HOSPITAL IN A LIMITED ACCESS AREA WITH THE HIGHEST BED NEED SHALL RECEIVE 10 POINTS. ALL OTHER APPLICANTS SHALL RECEIVE POINTS as set forth in the following table.

BED NEED	POINTS AWARDED
Applicant IN LAA WITH HIGHEST BED NEED	10 pts
All other applicants	Bed need of the applicant's project divided by the bed need of the applicant with the highest bed need, then multiplied by 10
Example: The highest applicant proposes project in LAA allowing 22 beds	10 points
Applicant proposes project in LAA allowing 15 beds	$(15 \div 22) \times 10 = 6.8$ is 7 points
Applicant proposes project in LAA allowing 10 beds	$(10 \div 22) \times 10 = 4.5$ is 5 points

POINTS shall be rounded to the nearest whole number.

6. Other technical edits.



Oral comments may be presented during the hearing on Thursday, July 29, 2021, or submitted in writing by sending an email to the following email address: MDHHS-ConWebTeam@michigan.gov

Please submit written comments no later than 5:00 p.m., Thursday, August 5, 2021.

If you have any questions or concerns, please contact Tania Rodriguez at rodriguez1@michigan.gov.